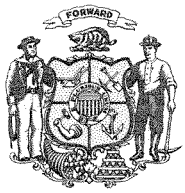
WISCONSIN STATE SENATE



Carol Roessler
STATE SENATOR

To: Members of the Senate Committee on Health, Children, Families, Aging and Long Term Care

From: Senator Carol Roessler, Chair

Date: August 27, 2004

Re: Clearinghouse Rule 04-055 relating to Wisconsin's statewide trauma care system.

CR 04-055 has been referred to the Senate Health, Children, Families, Aging and Long Term Care Committee. CR 04-055 governs the development and operation of Wisconsin's Statewide Trauma Care System.

If you would like the committee to hold a hearing on CR 04-055, please contact Jennifer Stegall in my office by September 7, 2004.

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State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Helene Nelson, Secretary

August 20, 2004

The Honorable Alan J. Lasee, President
Wisconsin State Senate
17 West Main St., Room 401
Madison, WI 53702

The Honorable John Gard, Speaker
Wisconsin State Assembly
17 West Main St., Room 208
Madison, WI 53702

Re: Clearinghouse Rule 04-055

Gentlemen:

In accordance with the provisions of s. 227.19 (2), Stats., you are hereby notified that the above-mentioned rules are in final draft form. This notice and the report required by s. 227.19 (3), Stats., are submitted herewith in triplicate.

The rules were submitted to the Legislative Council for review under s. 227.15, Stats. A copy of the Council's report is also enclosed.

If you have any questions about the rules, please contact Marianne Peck at 266-0601.

Sincerely,

Helene Nelson
Secretary

cc Gary Poulson, Assistant Revisor of Statutes
Senator Joseph Liebham, JCRAR
Representative Glenn Grothman, JCRAR

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FOR

Helene Nelson
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Senator Joseph Liebham, JCRAR
Representative Glenn Grothman, JCRAR

PROPOSED ADMINISTRATIVE RULES – CR04-055;
HFS 118 Trauma Care
ANALYSIS FOR LEGISLATIVE STANDING COMMITTEES
PURSANT TO S. 227.19 (3), STATS.

Basis and Purpose of Proposed Rules

The Department proposes to create ch. HFS 118, rules governing the development and operation of Wisconsin's Statewide Trauma Care System. The system's objective is to reduce death and disability resulting from traumatic injury by:

- Decreasing the incidence of trauma;
- Providing optimal care of trauma victims and their families; and
- Collecting and assessing trauma-related data.

Trauma is a sudden physical injury caused by the application of an external force or violence, such as a motor vehicle crash, a fall or a blow from a blunt or penetrating instrument. Trauma is the leading cause of death in Wisconsin among people under age 35 and is the fourth leading cause of death among the general Wisconsin population. Traumatic injury and its resultant care may, directly or indirectly, affect all Wisconsin residents and visitors. Section 146.56, Stats., directs the Department of Health and Family Services to develop and implement a statewide trauma care system. Through a statewide trauma system, health care and public safety participants will best be able to respond to and address the needs of trauma victims and their families. The Statewide Trauma Advisory Council, established under s. 15.197 (25), Stats., and appointed by the Secretary of the Department of Health and Family Services, has been collaborating with the Department for the past four years towards the development and implementation of Wisconsin's Statewide Trauma Care System. Wisconsin's Statewide Trauma Care System, when fully implemented, will enhance community health through an organized system of injury prevention, acute care and rehabilitation that is fully integrated with the public health care system in a community.

The Department is proposing the following through its creation of chapter HFS 118:

- A method by which to classify the emergency care capabilities of all Wisconsin hospitals;
- Use of the American College of Surgeons publication, *Resources for Optimal Care of the Injured Patient: 1999*, to evaluate the adequacy of hospitals' trauma care capabilities;
- Policies guiding the development and use of Regional Trauma Advisory Councils for the purpose of developing, implementing and monitoring the trauma care system; and
- Policies governing the establishment and operation of a statewide trauma registry; triage and transfer protocols among trauma care providers; and the promotion of improved trauma care provider performance.

Data collected from the state trauma registry on injury incidence, patient care and outcomes, specified in section HFS 118.09, will help identify problems and evaluate the performance of the existing trauma care system. Through this information, communities will be able to assess the nature of traumatic injuries in Wisconsin and establish appropriate injury prevention programs to reduce the occurrence of injuries, expedite patients' recovery and minimize the lasting effects of injuries.

Section 146.56 (2), Stats., authorizes the Department to develop and promulgate rules necessary to implement the trauma care system. The rules must include a method by which to classify all hospitals as to their respective emergency care capabilities. The classification rule must be based on standards developed by the American College of Surgeons.

Changes to Rulemaking Order Analysis or Fiscal Estimate

- *Changes to Rulemaking Order Analysis*

In response to public comments, the Department:

1. Modified its definitions of "bypass," "executive council," "indicator review" and "level IV" (trauma care facility) in HFS 118.03.
2. Included revising administrative rules to the list of lead agency responsibilities in HFS 118.04 (2) (a).
3. Modified HFS 118.04 (4) to require that the Department give 24 hours advance notice to providers before examining provider equipment or records, and limit the Department's investigative scope to issues associated with complaints.
4. Added a note to HFS 118.04 (6) (a) 4. a. that suggests the minimal composition of a trauma facility site visit team.
5. Modified HFS 118.06 (3) (c) 1. e. to give RTACs the option of designating a resource hospital in an adjoining state that has trauma care resources that are equivalent to an ASC-verified Level I or II hospital.

In response to Clearinghouse comments, the Department:

1. Made a variety of technical changes to the order.
2. Changed the definitions of "bypass" and "emergency medical technician."
3. Deleted the definitions of "major trauma" and "primary membership."
4. Explained what a trauma care geographic region is under HFS 118.04 (2) (b).
5. Clarified the identity of the parties who the Department is responsible for resolving conflicts between or among under HFS 118.04 (2) (g) and who the RTAC is responsible for resolving conflicts between or among under HFS 118.06 (3) (m).
6. Clarified in HFS 118.06 (3) (b) 1. g. that persons may not serve on more than one RTAC executive council.
7. Added first responder services to the entities that the Department asks to collect trauma injury data under HFS 118.09 (2).
8. Modified HFS 118.10 (3) (h) to clarify Department expectations for maintaining confidentiality of data used in the performance improvement process.
9. Deleted HFS 118.10 (3) (i) because it is unnecessary insofar as it repeats the requirement under HFS 118.06 (3) (m).

- *Changes to Fiscal Estimate*

The Department has made no changes to its original fiscal estimate.

Responses to Clearinghouse Recommendations

With the following exceptions, the Department accepted all of the comments offered by the Legislative Council Rules Clearinghouse comments and modified the rulemaking order accordingly.

Comment 5.q.: With respect to s. HFS 118.04 (3) (a) 2., should there be a timeline for when an investigation must be commenced or completed?

Response: The Department cannot specify a completion time for investigations because the completion time will depend on the nature of the complaint or problem that prompted the investigation. The Department has inserted a note to this effect in the rule.

Comment 5.r.: The text should be reviewed and clarified as to whether the investigation authority applies only in response to complaints or applies more broadly.

Response: The Department has added language that clarifies that the Department's investigative scope is limited to that which pertains to the nature of the complaint.

Effect on Small Business

These proposed rules will require ambulance services to complete reports pertaining to their trauma care activities.

Comments on Proposed Rule

- Public Hearing Summary

The Department held six public hearings in the five public health regions, including two hearings in Madison. Marianne Peck, the State Trauma Care System Coordinator, and Nan Turner, the Emergency Medical Services Licensing and Section Chief, staffed the hearing. Twenty-seven people attended the hearings. Eleven persons provided oral or written testimony in favor of the proposed rule, one person provided oral testimony against the proposed rule as written, and fifteen persons simply observed the proceedings. The Department's comment period remained open until Friday, August 6, 2004. The Department received no additional comments during the public comment period. The specific comments and the Department's responses to the comments are contained on a subsequent table at the end of this report.

- Public Comments Summary

The Department worked extensively and collaboratively with the State Trauma Advisory Council, the EMS Advisory Board, hospital and other trauma care and injury prevention participants prior to and during the drafting of the initial proposed rulemaking order. As a result, the comments provided to the Department at the public hearing were largely supportive of the proposed revisions. Many of the comments concerned whether and how the Department would fund and allocate resources to operate and evaluate the state trauma care system and to provide sanctions for non-compliance. Though the Department recognizes these comments as substantial and accurate, they need to be addressed statutorily and in budget allocations, rather than in administrative rules. Some comments also expressed concern about whether RTAC members would be protected from civil suits if the RTAC determined that provider practices needed to be changed. The Department believes that these concerns would best be addressed through statutory change by the Legislature.

Some comments asked for clarification of definitions in the chapter, while one comment stressed the importance of addressing the pediatric population in the trauma care system. The Department acknowledges that the care of the pediatric trauma patient and preventing the injuries associated with children are essential components of the trauma system. However, the Department anticipates that each individual region, through the collection and analysis of pediatric trauma data, and through the region's trauma plans, will best address pediatric trauma care. With experience, the needs of the pediatric population will become more evident, and Wisconsin, with adequate resources, may choose to expand it's state trauma care facility classification system to include different levels of pediatric trauma facilities. Under the current proposed rules, moreover, any hospital may choose to become an American College of Surgeons Verified Pediatric Trauma Center.

- List of Hearing Attendees and Commenters

The following is a complete list of the people who attended a public hearing and completed a registration form, or submitted written comments via letter, fax or e-mail on the proposed creation of

HFS 118 Trauma Care Rulemaking Order. Associated with each person's name and affiliation is an indication of the person's position on the proposed rules and whether or not the person testified or provided written comments. The number associated with a person in this table corresponds to comments that person made in the subsequent table entitled, "Public Comments and department Responses."

Name and Address/ Affiliation	Position on Revision	Action
1. William Bazan 3200 W. Highland Blvd. Milwaukee, WI 53208 Wisconsin Hospital Association	Supports proposed rule	Oral and written testimony
2. Joseph J. Ketarkus 202 So. Park St. Madison, WI 53715 Meriter Hospital	Supports proposed rule	Oral and written testimony
3. Bonnie Stamm 202 So. Park St. Madison, WI 53715 Meriter Hospital	Supports proposed rule	Observed at hearing
4. Peggy A. Rosenzweig Lobbyist-Statewide Wisconsin Emergency Room Physicians No address given	No Comments	Observed at hearing
5. Mary Jean Erschen 3348 Ambassador Dr. #4 Madison, WI 53718 Wisconsin Center for Emergency Health and Safety for Schools and self	Supports proposed rule	Oral and written testimony
6. Holly Hepp 3819 S. 19th St. Milwaukee, WI 53221 Wisconsin trauma and self	Supports proposed rule as written	Observed at hearing
7. Leif Erickson 10400 75th St. Kenosha, WI 53142 EMS Coordinator Aurora Medical Center-Kenosha	Supports proposed rule as written	Observed at hearing
8. Rebecca Schwulchow 27823 99th St. Trevor, WI 53179 Represents self	No comments	Observed at hearing
9. Gloria Murawsky 711 W. Wells St. Milwaukee, WI 53233 Milwaukee Fire Department	Supports the proposed rule as written	Observed at hearing
10. Pepie S. DuDeVoire 711 W. Wells Milwaukee, WI 53233 Milwaukee Fire Department	Supports proposed rule as written	Observed at hearing
11. John Walsh 500 S. Oakwood Rd. Oshkosh, WI 54904 Affinity Health System	Supports proposed rule	Oral and written testimony

Name and Address/ Affiliation	Position on Revision	Action
12. Ann Younger Crandall 130 2nd St. Neenah, WI 54957-2021 Theda Care, Inc. and Theda Star Air Medical	Supports proposed rule as written	Written testimony
13. Kelly Stanislaus 130 2nd St. Neenah, WI 54956 Theda Clark Medical Center	Supports proposed rule as written	Written testimony
14. Jennifer Gerdmann 425 Steven St. Green Bay, WI 54303 St. Vincent Hospital	Supports proposed rule as written	Written testimony
15. Linda McIntyre 2321 Stout Rd. Menomonie, WI 54751 Myrtle Werth Hospital and Red Cedar Clinic	No comments	Observed at hearing
16. Tom Thorsness 900 West Clairemont Ave. Eau Claire, WI 54701 Sacred Heart Hospital	No comments	Observed at hearing
17. Karen King E 3202 770th Ave. Menomonie, WI 54751 North/Northwest Regional Trauma Advisory Council	No comments	Observed at hearing
18. David Cirisi, MD 1400 Bellzer St. Eau Claire, WI 54702 Luther Hospital	Supports proposed rule as written	Oral testimony
19. Merrilee Carlson 123 East 8th St. Ashland, WI 54806 Lake Superior Regional Trauma Advisory Council and Memorial Medical Center of Ashland	Supports the proposed rule as written	Oral and written testimony
20. Sarah Trunkel 216 Sunset Place Neillsville, WI 54456 Represents self	No comments	Observed at hearing
21. Judy Jones 3231 Eastlawn St. Eau Claire, WI 54703 Represents self	No comments	Observed at hearing
22. Robin Schultz Sacred Heart Hospital 900 W. Clairemont Ave. Eau Claire, WI 54701 EMS Coordinator - Sacred Heart Hospital	No comments	Observed at hearing
23. David A. Gee, Deputy Chief 216 So. Dewey St. Eau Claire, WI 54703 Eau Claire Fire and Rescue	Supports proposed rule	Written comments
24. Kathe Miranowski 2123 Providence Ct.	Opposes rule as written	Oral testimony

Name and Address/ Affiliation	Position on Revision	Action
Eau Claire, WI 54703 Represents self		
25. Carol Immermann N2232 Willow Way La Crosse, WI 54601 Franciscan Skemp Hospital Systems	Supports the proposed rule as written	Oral and written testimony
26. Sandra K. Eustice 3811 Fairfax Eau Claire, WI 54701 Represents self	Supports the proposed rule as written	Observed at hearing
27. Tim Hestad Rice Lake Represents self	No comments	Observed at hearing

Public Comments and Department Responses

Comment Sequence Number and Rule Reference (as found in the initial proposed rule order)	Comment (numbers are associated with person listed on the list of hearing attendees and commentaries)	Department Response
1. General	Supports the proposed rule, however would like clarification on how the process through sanctions for noncompliance will be implemented. For example, how will regulatory oversight for compliance occur, what are the sanctions, will there be financial penalties, will there be audits, can the department terminate someone's ability to operate? **(2)** Supports the rules as written, but suggests that the Department in the future clarify the consequences for EMS services or medical facilities who choose not to follow the rules. **(12)**	The Department has attempted to specify rules that guide the system's development and promote a coordinated and effective system of trauma care. The Department's rulemaking order proposes to require EMS providers to state in their operational plans which RTAC they have chosen to participate in. Given the voluntary nature of Wisconsin's system, providers who choose not to follow ch. HFS 118 or meaningfully participate in cooperative efforts to improve our state's efforts to improve the provision of trauma care, at minimum, jeopardize the Department's recognition of their role in the system. Beyond, this, however, the ramifications of not following the ch. HFS 118 rules remains to be seen. If Wisconsin's trauma care providers cannot cooperatively work together to provide an effective trauma care system, the Legislature has the option of amending s. 146.56, Stats., to give the Department greater authority to enforce compliance with ch. HFS 118.
2. General	Supports the proposed rule because other states with experienced trauma systems have shown it provides optimal care and reduces morbidity and mortality in all age groups. **(5, 13)**	No response necessary.
3. General	Supports the proposed rule because it decreases the cost burden of trauma on our society. **(5)**	No response necessary.
4. General	Support of the proposed rule because data collection is essential and critical in identifying accident trends to establish injury prevention initiatives appropriate to specific areas within the state. Loss of life and life-long disabilities certainly indicate and are supported by factual data, and would be substantially reduced by a trauma system. **(5, 11)**	No response necessary.
5. General	Supports the proposed rule because systems of emergency care for threats of terrorism are needed, as are Regional Trauma Advisory Councils (RTACs).Moreover, a well-functioning trauma system would result in positive recognition to the Emergency Medical Services (EMS) profession. **(5)**	No response necessary.
6. General	Supports proposed rule for injury prevention programs that involve all citizens and are integrated into education from preschool through 12th grade. Trauma is the leading	No response necessary.

	cause of death for children, so the trauma system is vital for the enhancement of the children. The state trauma plan encompasses injury prevention initiatives to prevent injuries from occurring. **(5, 13)**	
7. General	Pediatric integration into the rules is essential and the needs of pediatric patients need to be separated from the adult needs or they will get missed in the implementation of the trauma system. Classification of hospitals should include pediatric classifications according to the American Academy of Pediatrics' Guidelines along with the American College of Surgeons and those resources need to be known to the EMS community. **(5)**	The Department agrees that the care of the pediatric trauma patient is of paramount importance to Wisconsin residents. Pediatric trauma patients require care and prevention techniques unique to children. The Department expects each region to incorporate the special needs of the pediatric patient in the region's protocols and trauma plans. As the lead agency, the Department wants to ensure that children's needs are not overlooked. However, the Department believes it would be best to delay further pediatric facility classification until the state trauma care system matures and it becomes more apparent whether additional resources become available to define pediatric trauma facility classifications. Notwithstanding the Department's preliminary focus on adult trauma care, any hospital may seek ACS verification for pediatric care.
8. General	Supports the trauma system and budget proposal and suggests that the Department establish and impose a fee on all individuals who receive a vehicle moving citation because such offenders are more likely to be involved in a motor vehicle crash. Would like to see increased funding for EMS, but trauma system needs to have own source of funding. **(11)**	The merits of the commenter's suggestion aside, the Department simply does not have the authority to impose such a fee. The Legislature would need to establish such authority, but, having done so, the authority would most likely be given to the Department of Transportation as an adjunct to the current system of moving vehicle monetary fines.
9. General	Supports the proposed rule because Wisconsin does not have a trauma system and the death/injury numbers are increasing. Trauma victims are dying because they are not matched with the appropriate resources and Wisconsin has a large rural population with limited trauma resources. There are trauma centers, helicopters and paramedic services available in the state that could be utilized to care for the injured patient. Supports the rule's requirements that RTACs develop a trauma plan; and that hospitals be classified as trauma care facilities based on their available resources. Also supports the definition of a major trauma patient and the development of EMS service plans that will help providers know what resources are available in the region and state. **(13)**	No response necessary.
10. General	Supports HFS 118 as written. Believes that Wisconsin is in dire need of a trauma system. Many hours have been put into this project - it will decrease potential pain and	No response necessary.

	suffering of crash victims in Wisconsin. **(14)**	
11. General	Supports the rule as written and would like to see regional coordinators. Currently, system is voluntary and the work involved in running an RTAC is phenomenal. A coordinator would benefit the system and increase cohesiveness, and it should be a state-paid position. There should be language in the rules addressing funding for the system and covering administrative costs for RTACs. **(19, 24)** Supports the rule because it would improve patient care. If done correctly, and with well-written guidelines and protocols, patient care would improve. Supports the concept of paid regional directors. Without paid regional directors, the system will probably falter. **(23)**	The Department's ability to maintain and financially support a regional coordinator staff position is dependent on available funding for such a position. Currently, the Department does not have sufficient resources for such positions. The Department cannot specify, by rule, funding for the activities of a regional coordinator.
12. General	Represents three hospitals and generally supports the trauma program, especially for rural hospitals. The rules are not burdensome nor a financial hardship. By raising awareness, there has already been a difference by patients getting to the right hospital. Setting up minimal guidelines will help save lives. **(25)**	No response necessary.
13. HFS 118.03 (5)	The definition of "bypass" refers to a higher level of care. The definition should refer instead to the resource capability of each hospital. **(24)**	The Department agrees that the definition's wording can be improved and has modified the definition to read as follows: "'Bypass' means to forego delivery of the patient to the nearest hospital for a hospital whose resources are more appropriate for the patient's injury pursuant to direction given to a pre-hospital emergency medical service by on-line medical direction or predetermined triage criteria."
14. HFS 118.03 (12)	The rules define the Executive Council as a decision-making body. The Executive Council should instead be referred to as the RTAC's "leadership" body. Most decisions will go to the RTAC membership for a vote rather than just the Executive Council. **(24)**	The Department agrees and has changed the language to read: "'Executive council'" means the RTAC leadership body, which is composed of professionals from each region who reflect trauma care expertise, leadership and diversity within each trauma care region."
15. HFS 118.03 (18)	Questioned whether the definition of "indicator review" is accurate. Suggested that the appropriate term may be "audit review." **(24)**	Since measurement of trauma system performance include not only outcomes, but also processes, the Department has agreed to change the definition to read: "'Indicator review' means the RTAC's assessment of trauma system performance based on desired trauma system measurements and used by the RTAC in the performance improvement process."
16. HFS 118.03 (20, 21)	The commenter questions whether Level I and II verification requirements are in the rules and whether the verification expectations should be included in the Level I and II definitions. **(24)**	The placement of substantive material in rule definitions is not done in Wisconsin administrative rules because the content of definitions are not legally enforceable. Therefore, the Department specified the American College of Surgeons Level I and II verification requirements in HFS 118.08 (2). Given that the ACS verification requirements are lengthy,

		rather than specify those requirements in HFS 118.08 (2), the Department received permission from the Attorney General to instead incorporate the ACS national standards by reference into administrative rule. The note following HFS 118.08 (2) describes where interested persons may obtain a copy of the ACS standards.
17. HFS 118.03 (23)	The definition of a level IV trauma care facility should read as follows: "Level IV" means a class of trauma care facility that is characterized by the hospital's ability to stabilize and provide advanced trauma life support prior to patient transfer. Omit the phrase "in remote areas where no higher level of care is available." This change is recommended to maintain the voluntary nature of the hospital's self-assessment process. **(1)**	The Department agrees and has changed the language accordingly.
18. HFS 118.04 (2) (a)	The general duties of the lead agency should be stated as follows: "Develop and revise administrative rules for the statewide trauma care system." This change provides for greater input from all the stakeholders in the trauma care system. **(1)**	The Department agrees and has added the phrase "and administrative rules" to the Department's duties. The Department has retained the reference to revising guidelines to preserve its ability to influence the future development of the trauma care system.
19. HFS 118.04 (3)	RTACs are a voluntary body and should not be asked to investigate and respond to complaints. The state should be responsible and work collaboratively with the RTAC. **(24)**	The Department disagrees that it should be solely responsible to investigate and respond to complaints. In many cases, the regional trauma advisory council is in the best position to respond to issues that may be solely a regional issue. The Department's appropriate role is to assist RTACs' investigation of issues involved in a complaint, if needed, but RTACs, in their exercise of local oversight, should be in the best position to knowledgeably address issues associated with a complaint.
20. HFS 118.04 (3) (b) 2.	What about the RTAC confidentiality if the department investigates a complaint? **(24)**	Regardless of whether the Department or the RTAC is responsible for or takes the lead in resolving a particular complaint, both the Department and the RTAC are responsible for maintaining patient confidentiality to the extent required under existing state and federal laws. Those laws apply to patient information used under this chapter, and nothing the Department specifies in this rule could change or override that applicability. Both the Department and RTACs must take such steps as are necessary to ensure that their actions comply with all applicable patient confidentiality laws.
21. HFS 118.04 (4)	Omit the words "without advance notice." If the investigation of a hospital or emergency vehicle is to be accomplished efficiently, advance notification will make the process much more productive for both the entity and the authorized agent of the department. **(1)**	The Department agrees and has changed the language to read as follows: "An authorized employee or agent of the department, upon presentation of identification, shall be permitted to examine equipment or vehicles or enter the offices of an RTAC, a hospital seeking or having department recognition as a trauma care facility or an ambulance service provider during business hours with **24 hour** advance notice or at any other reasonable prearranged time."
22. HFS 118.04 (4)	The implementation phase of the trauma care system appears to be switching from voluntary to mandatory. The Bureau as the lead agency has authority over EMS, but	The Department disagrees with the contention that the implementation phase of Wisconsin's trauma care system has transitioned from being voluntary to mandatory. Provider participation in the trauma care system is voluntary. However, as lead agency, the Department must specify

	how will this work system-wide? **(18)** How will regulatory authority go regarding hospitals particularly investigations? **(18)**	parameters and expectations for the system's operation in order for the system to function in a coordinated fashion. The Department has been directed by the Legislature to guide the development and implementation of the trauma care system. This requires the Department to influence the activities of trauma care system providers, including hospitals and EMS providers. The Department has attempted to do so, through its proposed rules, as minimally as possible, consistent with its legislative directive. Investigating complaints is a part of the Department's role in assuring the continuing improvement in the performance of the state's trauma care system.
23. HFS 118.04 (6) (a) 3.	Clarify the statement, "The department may require a hospital to document the basis for the hospital's professed level of trauma care facility." **(24)**	The Department believes that this statement, expressed in s. 146.56(2), Stats., is sufficiently clear as it is written. While the Department cannot direct a hospital to establish and provide the resources commensurate with being classified as a particular level of trauma care facility, the Department needs to ensure its ability to request from a hospital sufficient and appropriate documentation of the hospital's basis for its chosen self-classification.
24. HFS 118.04 (6) (a) 4.	State budget cutbacks have limited some services the State is able to provide. This requirement appears to add an additional burden to the state, and DHFS may not have enough staff and resources to support the responsibility of performing site visits. **(2)**	The Department agrees that resources for administration and oversight of the trauma care system are limited. As the note after HFS 118.04 (6) (a) 4. indicates, site visits will frequently be staffed by non-Department employees. The Department currently does not anticipate having funding for these persons either. Regardless, the Department believes that site visits by qualified professionals are the best means of verifying information provided by hospitals. For the immediate future, persons who conduct site visits (as well as persons generally providing time towards the successful implementation of the state's trauma care system) will be asked to do so voluntarily.
25. HFS 118.04 (6) (a) 4. a.	There should be some requirements for the site visit team. **(24)**	The Department agrees and has added a note containing its recommendations for the composition of the site visit team. As stated in the note, the team would include a trauma surgeon, a trauma coordinator and an emergency department physician. Each of these persons, minimally, would be employed by or associated with an ACS-verified trauma facility. The Department added a note because it did not want to require a particular team composition that may not always be feasible given limited resources.
26. HFS 118.05	Add another STAC responsibility, which would read: "Recommending to the department that an administrative rules process be initiated for any changes and/or modifications to the Scope of Practice Statement for Interfacility Transfers." The rationale for this is to provide hospitals, especially rural hospitals, and emergency medical service agencies the opportunity to provide input to proposed changes so as not to compromise patient care. **(1)**	Interfacility transfers are addressed under chapters HFS 110, 111 and 112. Notwithstanding this, HFS 118.05 (1), in stating that the STAC is responsible for "advising the Department on issues related to the development, implementation and evaluation of the statewide trauma care system," already has the authority to suggest that the Department modify its rules relating to interfacility transfers.
27. HFS 118.06 (3)	Will members of RTACs that are involved in the regulatory expectations be compensated? What happens if the RTAC members do not agree to accomplish the necessary work without compensation? **(18)**	The Department knows of no funds currently available for compensating RTACs or their members for their services. If persons responsible for providing trauma care in Wisconsin do not devote requisite time and energy toward improvement of the state's trauma care system, the goals of 1997 Wisconsin Act 154 (s. 146.56, Stats.) will not be accomplished.

28. HFS 118.06 (3)	The rules request RTACs to meet deadlines and submit reports and plans. How can volunteers accomplish this without state-paid employees in place? **(24)**	The Department acknowledges that needed funding has not been made available for RTACs; a situation that may or may not change in the future. However, given that virtually all trauma care system participants agree on the need for system-wide trauma care planning and provider coordination, the Department (and perhaps, the Legislature) believes that participation by all persons involved in trauma care is an incumbent responsibility of trauma care providers that is part and parcel of their professional work. While the Department hopes that there will be financial assistance for RTACs in the future, the Department believes it would be unwise to wait for funding for implementation of the activities specified in these proposed rules.
29. HFS 118.06 (3) (c) 1. e	Border states may not have a trauma system and may not use ACS criteria. RTACs may still need that hospital to serve as a resource hospital. **(24)**	The Department agrees and has modified the proposed language to give RTACs the option of designating a resource hospital in an adjoining state that has trauma care resources that are equivalent to an ASC-verified Level I or II hospital.
30. HFS 118.07 (2)	Define participation. **(24)**	As the note after subsection (2) indicates, the Department believes that minimally adequate participation means that an ambulance service provider selects one RTAC for their primary membership.
31. HFS 118.08 (2) (a) 1. b. and c.	Questions whether the Department is going to levy a fee on hospitals that wish to be classified as Level III or IV trauma care facilities. **(25)**	While hospitals will be responsible for the cost of becoming a state classified Level I, II, III or IV trauma care facility, the Department does not intend to charge a fee to become state-classified.
32. HFS 118.09	Concerned about whether the trauma registry software and data collection process will capture trauma data from any facility regardless of the trauma registry each facility uses. Desires that the trauma registry package selected by the Department accommodate any registry that hospitals are using. Wants Department to clarify whether DHFS staff will be available to help support this process. **(2)**	The Department intends to provide limited staff support to guide the collection and use of Trauma Registry data. The Department acknowledges the need to focus data collection and use to the greatest extent possible while ensuring that the data collected allows meaningful analysis to be performed. Therefore, in implementing this aspect of ch. HFS 118, the Department intends to remain sensitive to the needs of both data collectors and those who are responsible for evaluating the data.
33. HFS 118.09; HFS 118.10	How will the Registry process work when there is no legislative language to protect health care providers from civil lawsuits? **(18)**	The Department believes that section 146.37, Stats., may provide adequate protection to providers responsible for collecting and analyzing trauma care system data. However, the Department is also working to add statutory language that more clearly provides such assurances and protections.
34. HFS 118.10 (2), (3) (h)	Clarify rule language that provides immunity from violating patient confidentiality for process improvement and case review necessary for injury prevention. All health systems must follow strict requirements to protect patient confidentiality. Rule not completely clear how patient confidentiality will be protected in these instances. There is no liability protection language for regional trauma advisory councils if the patient has a poor outcome. **(2, 24)**	The Department believes that s. 146.37, Stats., may provide sufficient civil immunity to persons acting in good faith. If not, the Department currently lacks the authority to grant, in rules, immunity to persons who violate patient confidentiality laws. The Department believes that such a grant needs to be made in statute, and the Department is working to add such language. Finally, each RTAC should specify a procedure to ensure confidentiality throughout the performance improvement process.

DEPARTMENT OF HEALTH AND FAMILY SERVICES
Office of Legal Counsel
EXS-282 (2/04)

STATE OF WISCONSIN

FISCAL ESTIMATE FOR ADMINISTRATIVE RULES

☒ Original ☐ Updated		LRB Number	Amendment Number if Applicable
☐ Corrected ☐ Supplemental		Bill Number	Administrative Rule Number HFS 118

Subject
Wisconsin trauma Care System

Fiscal Effect
State: ☒ No State Fiscal Effect
Check columns below only if bill makes a direct appropriation or effects a sum sufficient appropriation.
☐ Increase Existing Appropriation ☐ Increase Existing Revenues
☐ Decrease Existing Appropriation ☐ Decrease Existing Revenues
☐ Create New Appropriation

☐ Increase Costs – May be possible to absorb within agency's budget.
☐ Yes ☒ No
☐ Decrease Costs

Local: ☒ No Local Government Costs
1. ☐ Increase Costs ☐ Permissive ☐ Mandatory
2. ☐ Decrease Costs ☐ Permissive ☐ Mandatory
3. ☐ Increase Costs ☐ Permissive ☐ Mandatory
4. ☐ Decrease Costs ☐ Permissive ☐ Mandatory

5. Types of Local Government Units Affected:
☐ Towns ☐ Villages ☐ Cities
☐ Counties ☐ Others:
☐ School Districts ☐ WCTS Districts

Private: ☒ No Private Sector Costs
1. ☐ Increase Costs
2. Amount of Increase

3. Private Entities Affected

Fund Sources Affected	Affected Chapter 20 Appropriations
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S	None

Assumptions Used in Arriving at Fiscal Estimate

Section 146.56 of the statutes mandates a statewide trauma care system and requires the Department to promulgate rules to develop and implement the system. The statutes also require the Department to develop Regional Trauma Advisory Councils (RTACs). The rule requires hospitals to become affiliated with a Regional Trauma Advisory Council by December 31, 2004. There will be no fiscal effect as a result of this requirement.

Under this statute, hospitals are required to certify to the Department the classification level of trauma care services they provide. Trauma facilities are classified as Level I, II, III, or IV, depending on the comprehensiveness of the trauma care provided. Each hospital determines the level of trauma facility care for which it qualifies. If a hospital wishes to become a Level I or Level II trauma care facility, it must receive verification from the American College of Surgeons (ACS). Hospitals not seeking to obtain Level I or II trauma status need only do a self-report survey.

This rule requires hospitals to report the level of their trauma facilities to the Department. The rule does not require that hospitals attain a certain level of facility. Any costs that hospitals incur in becoming Level I or II facilities would be the result of the verification process, not the reporting requirement of the rule. There will, therefore, be no cost to hospitals as the result of this requirement.

The rule requires Emergency Medical Services (EMS) to become affiliated with an RTAC. There will be no cost to EMS providers for this affiliation.

The rule establishes policies governing the operation of a statewide trauma registry and the promotion of improved trauma provider performance. When the registry is operational, hospitals and EMS providers will be required to submit trauma data on a quarterly basis to the registry. The Department will use this data to improve trauma care.

It is likely that most agencies will collect trauma data for their own purposes. Hospitals with Level I and Level II trauma centers, for example, are required to collect trauma data as a condition of their verification. The requirements of this rule are not expected to result in significant additional cost for agencies that are already collecting this data. To the extent that hospitals and EMS providers will be required to gather data that has not previously been collected, this requirement may result in some costs to these agencies. It is not possible to estimate these costs, but they are not expected to be significant.

There are no new local government requirements.

Long Range Fiscal Implications

PROPOSED ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
CREATING RULES

To create HFS 118, relating to Wisconsin's Statewide Trauma Care System.

Statute interpreted

The rules interpret s. 146.56, Stats.

Statutory authority

The Department's authority to create these rules is found in s. 146.56 (2), Stats.

Explanation of agency authority

Section 146.56 (2), Stats., authorizes the Department to develop and promulgate rules necessary to implement the trauma care system. The rules must include a method by which to classify all hospitals as to their respective emergency care capabilities. The classification rule must be based on standards developed by the American College of Surgeons.

Related statutes or rules

Several sections of chapter 146, Stats., relate to these rules. Section 146.50, relating to emergency medical services personnel, licensing and training, s. 146.53, relating to a state emergency medical services plan, s. 146.55, relating to emergency medical services programs, and s. 146.58, relating to the emergency medical services board, all relate to a trauma care system insofar as emergency medical services are the focal point of responding to traumatic events.

In addition, the Department has promulgated several chapters of administrative rules pertaining to emergency medical services. These rules correspond to the differing levels of competencies among emergency medical service personnel. Chapters HFS 110, 111 and 112 pertain to the licensing of different levels of emergency medical technicians. Chapter HFS 113 concerns the certification of first responders.

Plain language analysis

The Department proposes to create ch. HFS 118, rules governing the development and operation of Wisconsin's Statewide Trauma Care System. The system's objective is to reduce death and disability resulting from traumatic injury by:

- Decreasing the incidence of trauma;
- Providing optimal care of trauma victims and their families; and
- Collecting and assessing trauma-related data.

Trauma is a sudden physical injury caused by the application of an external force or violence, such as a motor vehicle crash, a fall or a blow from a blunt or penetrating instrument. Trauma is the leading cause of death in Wisconsin among people under age 35 and is the fourth leading cause of death among the general Wisconsin population. Traumatic injury and its resultant care may, directly or indirectly, affect all Wisconsin residents and visitors. Section 146.56, Stats., directs the Department of Health and Family Services to develop and implement a statewide trauma care system. Through a statewide trauma system, health care and public safety participants will best be

able to respond to and address the needs of trauma victims and their families. The Statewide Trauma Advisory Council, established under s. 15.197 (25), Stats., and appointed by the Secretary of the Department of Health and Family Services, has been collaborating with the Department for the past four years towards the development and implementation of Wisconsin's Statewide Trauma Care System. Wisconsin's Statewide Trauma Care System, when fully implemented, will enhance community health through an organized system of injury prevention, acute care and rehabilitation that is fully integrated with the public health care system in a community.

The Department is proposing the following through its creation of chapter HFS 118:

- A method by which to classify the emergency care capabilities of all Wisconsin hospitals;
- Use of the American College of Surgeons publication, *Resources for Optimal Care of the Injured Patient: 1999*, to evaluate the adequacy of hospitals' trauma care capabilities;
- Policies guiding the development and use of Regional Trauma Advisory Councils for the purpose of developing, implementing and monitoring the trauma care system; and
- Policies governing the establishment and operation of a statewide trauma registry; triage and transfer protocols among trauma care providers; and the promotion of improved trauma care provider performance.

Data collected from the state trauma registry on injury incidence, patient care and outcomes, specified in section HFS 118.09, will help identify problems and evaluate the performance of the existing trauma care system. Through this information, communities will be able to assess the nature of traumatic injuries in Wisconsin and establish appropriate injury prevention programs to reduce the occurrence of injuries, expedite patients' recovery and minimize the lasting effects of injuries.

Summary of, and comparison with, existing or proposed federal regulation

There are no federal regulations that pertain to trauma care at this time. Federal grant money exists for the development of state trauma systems, however, these monies are optional at this time.

Comparison with rules in adjacent states

- Iowa

Iowa enacted state legislation establishing a state trauma care system in 1995 and administrative rules in 1997. The system became fully operational in 2001. All 117 hospitals in the state participate in the trauma system. Iowa's enabling statute created a trauma system advisory council that has 20 members. Iowa's law also established a system evaluation and quality improvement committee as well as a trauma registry. Hospitals self-define their level of commitment. Once the hospital chooses the level at which it wants to be verified, the state health department verifies that the hospital meet the requirements for verification of that level of trauma capability. Hospitals that are not verified do not receive trauma patients by ambulance. The state health department does an onsite verification of Level 1, 2 and 3 (but not for Level 4) trauma facilities. Administrative rules for trauma care are contained in chapters 134 to 138 of the Department of Public Health's code. Those rules:

- Authorize the state health department to:
  - deny authorization for a hospital to be a trauma care facility;
  - issue a citation and warning;
  - place a trauma care facility on probation; and

- suspend or revoke existing trauma care verification authorization.

- Direct the department of health to investigate complaints.
- Direct the department to categorize hospitals as a particular level trauma care facility after conducting a site survey of every hospital.
- Allow the department to accept ACS verification as a substitute for department verification.
- Establish mandatory reporting of trauma care data for the department's use in compiling and maintaining a trauma care registry.
- Specify required health care professional trauma education and training by level of trauma care facility.
- Establish a statewide trauma system evaluation quality improvement committee to analyze trauma data and recommend improvements in the state's trauma system.

- Illinois

Illinois promulgated administrative rules for trauma care in 1995, and has revised them several times since then. The rules are in Subchapter H (515.2000 to 515.2200) of Part 515, of Title 77 of the Illinois Adm. Code. With the following exceptions, the topics addressed in the rule are comparable to those proposed by the Department of Health and Family Services in ch. HFS 118. The Illinois rules:

- Mandate the existence of at least one Level 1 (highest level) trauma care facility in each EMS region in the state.
- Require the state health department to conduct a site visit to each hospital that applies to be designated as a Level 1 or 2 trauma center.
- Authorize the state health department to immediately revoke a trauma center's designation.
- Direct the department to issue a violation notice and require the trauma center to submit a plan of correction to the department within 10 days if violation of the rules does not present substantial probability that death or serious physical harm will result.
- Are much more prescriptive regarding the specific criteria for trauma center Level 1 and 2 designation and ongoing operation. (HFS 118 places the onus for approval of Level 1 and 2 designation on the hospital's being verified as a Level 1 or 2 trauma facility by ACS; and DHFS relies on a hospital's operation in accordance with the ACS document insofar as trauma care facilities will be expected to conform in accordance with applicable sections of the ACS document.)
- List each specific type of information hospitals are to report for trauma registry. (HFS 118 simply states that the data items required to be reported will be contained in a DHFS data submission manual.)
- Specify trauma registry data confidentiality guidelines, along with persons who have access to the registry data.
- Prohibit the department of health from requiring hospitals to provide information on cases that are dated more than two years before the department's request for further information.
- Contain guidelines for patient evaluation and transfer.
- Authorize the department to delegate the designation of trauma centers to a local health department in an area where there are a lot of trauma centers (i.e., large cities).
- Require local health departments to submit to the department of health copies of all complaints within two working days after receipt and copies of all final investigation reports within 10 working days after the completion of the investigation.
- Require local health departments to submit to the department of health copies of quarterly trauma center focused outcome analyses.

- Assure the confidentiality of trauma center medical audit data, and grants immunity from civil liability to the same extent hospitals are given under section 10.2 of the state's hospital licensing act.
- Direct the state health department to annually distribute funds to all trauma centers in the state.

- Michigan and Minnesota

Michigan and Minnesota are two of only about six states that do not have an organized trauma network. However, both states are progressing towards the establishment of a statewide trauma care system. In Minnesota, following a couple of years during which support was organized, legislation either has already been or is likely to soon be introduced to authorize the state's organization for and establishment of a trauma care system. In Michigan, a group of surgeons and lawmakers has launched an effort to create a statewide trauma system. That effort came two years after a government-commissioned report found a number of problems with trauma care in Michigan, including a lack of trauma centers in the northern part of the state and the absence of a system to collect data about traumatic injuries. Michigan received a $38,000 federal grant to develop a plan for creating a statewide trauma care system.

Summary of factual data and analytical methodologies

The Department based its development of ch. HFS 118 on the Wisconsin Statewide Trauma Care System Report, completed in January 2001. The Report was a joint effort of the Department and the Statewide Trauma Advisory Committee. The Committee and its subcommittees were composed of statewide representatives of hospitals, emergency physicians, trauma nurses, fire departments, emergency medical service providers, and surgeons. The Trauma Care System Report and these proposed rules recognize the need for a continuum of care that provides a comprehensive approach to the triage, treatment, transport, and ultimate care of major trauma victims. The Advisory Committee and the Department have heavily relied on the document "*Resources for the Optimal Care of the Injured Patient: 1999*" written by the American College of Surgeons Committee on Trauma, in developing these rules.

Analysis and supporting documents used to determine effect on small business

This chapter will primarily affect Wisconsin hospitals, rural medical centers and ambulance service providers. Based on fiscal year 2002 data, three hospitals had annual revenues under $5 million. There are currently 456 ambulance service providers in Wisconsin. The Department does not have annual revenue data for ambulance service providers. However, the Department presumes that most, if not all, ambulance service providers have annual revenues under $5 million.

Under these proposed HFS 118 rules, the Department would require all ambulance service providers to affiliate and participate with a Regional Trauma Advisory Council (RTAC). The purpose of such affiliation is to participate in their region's trauma care system. The proposed rules require ambulance service providers to state their RTAC affiliation choice in the ambulance service provider's operational plan. Under chapter HFS 110, ambulance service providers already must submit operational plans to the Department. The Department collects operational plans to ensure the appropriate operation of ambulance services. There will be no additional cost to fulfill this obligation.

Under section HFS 118.09 of these proposed rules, the Department also intends to develop and publish a data submission manual that specifies what information ambulance service providers will need to collect and submit to the Department for the purpose of analyzing trauma injury and care. The purpose of the analysis is to reduce trauma care injuries and improve the performance of the

trauma care system. Such data collection is essential to evaluating and improving health status and system performance.

Section 227.114 (2) of the statutes lists a variety of methods for reducing the effect rules have on small businesses. These methods are:

- Establishing less stringent compliance or reporting requirements for small businesses;
- Establishing less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- Consolidating or simplifying compliance or reporting requirements for small businesses;
- Establishing performance standards for small businesses to replace design or operational standards required in the rule; and
- Exempting small businesses from any or all requirements of the rule.

The Department has chosen not to reflect any of the preceding methods in its requirements to collect and submit trauma care data because it believes that exempting or modifying individual entities from data collection and reporting responsibilities would compromise the quality and usefulness of information needed to protect and improve the public's health.

Anticipated costs incurred by private sector

The Department believes that these proposed rules will not impose appreciable costs on the private sector that entities do not already incur in the provision of trauma care.

Trauma facilities are state-classified as Level I, II, III or IV or "unclassified," depending on the comprehensiveness of the trauma care provided. As required under s. 146.56 of the statutes, this rule requires hospitals to report their level of emergency care capability to the Department. The rule does not, however, assign a level to any hospital, nor does the rule require any hospital to attain a certain level of trauma care facility. Each hospital determines the level of trauma facility care it provides and qualifies for against published national standards. Classification as a Level I or II trauma facility includes verification of that status by the American College of Surgeons (ACS). The initial cost for a trauma center verification visit from ACS is approximately $3,000 plus the expenses and honoraria for two trauma surgeons responsible for performing the ACS inspection. Any costs that hospitals incur in becoming a Level I or II trauma care facility would be the result of the verification process, not the reporting requirement of the rule. There will, therefore, be no cost to hospitals as the result of this requirement. The ACS re-verification cost would include the ACS administration fee of $2,200 plus the two surgeon's expenses and honoraria. Any hospital that chooses to be a state-classified Level III or IV trauma care facility must complete the Department's self-assessment checklist and application form. All hospitals that choose a Level I, II, III or IV state classification shall be responsible for expenses associated with the classification process. The Department cannot determine the cost to become state classified as a Level III or IV because that cost will be based on what existing trauma care capabilities the hospital already has. The expenses are the same across the board for Level I, II, III or IV to become ACS-verified.

The rule requires emergency medical services providers to become affiliated with an RTAC. There will be no cost to providers for this affiliation.

The rule also establishes policies governing the operation of a statewide trauma registry and the promotion of improved trauma provider performance. When the registry is operational, hospitals and EMS providers will be required to submit trauma data on a quarterly basis to the registry. The Department will use this data to improve trauma care. It is likely that most agencies will collect trauma data for their own purposes. Hospitals with Level I and Level II trauma centers, for

example, are required to collect trauma data as a condition of their verification. The requirements of this rule are not expected to result in significant additional cost for agencies that are already collecting this data. To the extent that hospitals and EMS providers will be required to gather data that has not previously been collected, this requirement may result in some costs to these agencies. It is not possible to estimate these costs, but they are not expected to be significant.

Effect on small business

These proposed rules will require ambulance services to complete reports pertaining to their trauma care activities.

Agency contact person

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Place where comments are to be submitted and deadline for submission

The Department opened the public comment period on the proposed rules on June 14, 2004 and closed it on August 6, 2004. During that period, persons had the opportunity to submit oral or written comments on the rules in person, via email and postal mail, and via the Internet at the Department's administrative rules website.

Rule text

SECTION 1. HFS 118 is created to read:

Chapter HFS 118

TRAUMA CARE

Subchapter I – General Provisions

HFS 118.01 Authority and purpose.
HFS 118.02 Applicability.
HFS 118.03 Definitions.

Subchapter II - Statewide Organization for Trauma Care

HFS 118.04 Lead agency.
HFS 118.05 Statewide trauma advisory council.
HFS 118.06 Regional trauma advisory councils.
HFS 118.07 EMS services.
HFS 118.08 Hospitals.

Subchapter III - Trauma Care Improvement

HFS 118.09 Trauma registry.
HFS 118.10 Performance improvement.

Subchapter I – General Provisions

HFS 118.01 Authority and purpose. This chapter is promulgated under the authority of s. 146.56 (2), Stats., to develop and implement a statewide trauma care system. The purpose of the statewide trauma care system is to reduce death and disability resulting from traumatic injury by decreasing the incidence of trauma, providing optimal care of trauma victims and their families, and collecting and analyzing trauma-related data.

HFS 118.02 Applicability. This chapter applies to all of the following:

(1) The department.

(2) All persons who are any of the following:

(a) An EMT – basic or EMT – basic IV.

(b) An EMT – intermediate.

(c) An EMT – paramedic.

(d) A medical director.

(e) A first responder.

(3) A hospital approved under subch. II of ch. 50, Stats., and ch. HFS 124, excluding hospitals whose principal purpose is to treat persons with a mental illness.

(4) An ambulance service provider licensed under s. 146.50, Stats., and chs. HFS 110, 111 and 112.

(5) A regional trauma advisory council developed by the department pursuant to s. 146.56 (1), Stats.

(6) Any health care provider involved in the detection, prevention or care of an injured person and is a member of a Wisconsin RTAC.

(7) A Wisconsin law enforcement agency that is a member of a Wisconsin RTAC.

HFS 118.03 Definitions. In this chapter:

(1) "Ambulance service provider" has the meaning specified in s. 146.50 (1) (c), Stats., namely, a person engaged in the business of transporting sick, disabled or injured individuals by ambulance to or from facilities or institutions providing health services.

(2) "ACS" means the American college of surgeons.

(3) "Assessment and classification criteria" means the required trauma care services and capabilities for a hospital to be classified as a Level III or IV trauma care facility.

(4) "Audit" means a close examination of a situation or event in a multidisciplinary peer review.

(5) "Bypass" means to forego delivery of a patient to the nearest hospital for a hospital whose resources are more appropriate for the patient's injury pursuant to direction given to a pre-hospital emergency medical service by on-line medical direction or predetermined triage criteria.

(6) "Classification" means the process whereby a hospital identifies its service level as a trauma care facility and the department reviews and approves the hospital as a provider of a level of trauma care services to meet the needs of the severely injured patient.

(7) "Coordinating facility" means an ACS verified level I or II hospital that has a collaborative relationship with the regional trauma advisory council and the department as specified under s. HFS 118.06 (3) (c).

(8) "Definitive care" means comprehensive care for the full spectrum of injuries beyond the initial assessment and resuscitation phase.

(9) "Department" means the department of health and family services.

(10) "Dispatch" means identifying and coordinating the emergency resources needed to respond to a specific traumatic injury or illness.

(11) "Emergency medical technician" or "EMT" means an individual licensed by the department under ch. HFS 110, 111 or 112 as an EMT-basic, EMT-basic IV, EMT-intermediate or EMT-paramedic.

(12) "Executive council" means the RTAC leadership body, which is composed of professionals from each region who reflect trauma care expertise, leadership and diversity within each trauma care region.

(13) "First responder" means a person who is certified under ch. HFS 113 and who provides emergency care to a sick, disabled or injured individual prior to the arrival of an ambulance as a condition of employment or as a member of a first responder service.

(14) "First responder service" means a group of persons licensed by the department as a first responder group under s. 146.50 (8), Stats., who are employed or organized to provide emergency care to sick, disabled, or injured individuals as a response for aid requested through a public service access point in conjunction with the dispatch of an ambulance, but who do not provide ambulance transportation of a patient.

(15) "Fiscal agent" means the person or organization responsible for transactions of RTAC funds.

(16) "Health care provider" means a medical professional who or organization that is involved in either the detection, prevention or care of an injured person and includes all of the following:

(a) A nurse licensed under ch. 441, Stats.

(b) A dentist licensed under ch. 447, Stats.

(c) A physician or physician assistant licensed under subch. II of ch. 448, Stats.

(d) A rural medical center, as defined in s. 50.50 (11), Stats.

(e) A hospital.

(f) An ambulance service provider.

(g) An emergency medical technician.

(h) A first responder.

(i) A doctor of podiatric medicine and surgery licensed under subch. IV of chapter 448, Stats.

(17) "Hospital" means entities approved under subch. II of ch. 50, Stats., and ch. HFS 124, including critical access hospitals, that routinely provide trauma care, excluding hospitals whose principal purpose is to treat persons with a mental illness.

(18) "Indicator review" means the RTAC's assessment of trauma system performance based on desired trauma system measurements and used by the RTAC in the performance improvement process.

(19) "Lead agency" means an organization or agency that serves as the focal point for program development on the local, regional and state level. In this chapter, the department serves as the lead agency.

(20) "Level I" means a class of trauma care facility that is characterized by the hospital's capability of providing leadership and total care for every aspect of traumatic injury from prevention through rehabilitation, including research.

(21) "Level II" means a class of trauma care facility that is characterized by the hospital's ability to provide initial definitive trauma care regardless of the severity of injury, but may not be able to provide the same comprehensive care as a level I trauma center.

(22) "Level III" means a class of trauma care facility that is characterized by the hospital's ability to:

a. Provide assessment, resuscitation and stabilization.

b. Provide emergency surgery and arrange, when necessary, transfer to a level I or II trauma facility for definitive surgical and intensive trauma care.

(23) "Level IV" means a class of trauma care facility that is characterized by the hospital's ability to stabilize and provide advanced trauma life support prior to patient transfer.

(24) "Loop-closure" means the process whereby an RTAC has identified a quality improvement problem, completed an evaluation, developed an action plan and notified appropriate health care providers of the results.

(25) "Medical director" means the physician who is designated in an EMT operational plan to be responsible for all of the following off-line medical direction activities:

(a) Controlling, directing and supervising all phases of the emergency medical services program operated under the plan and the EMT's performing under the plan.

(b) Establishing standard operating protocols for EMTs performing under the plan.

(c) Coordinating and supervising evaluation activities carried out under the plan.

(d) Designating on-line medical control physicians, if the physicians are to be used in implementing the emergency medical services program.

(26) "Needs assessment" means a written report prepared by an RTAC identifying and documenting trauma care and injury prevention resources and deficiencies within a defined area of the trauma system and which serves as the basis for developing a regional trauma plan.

(27) "Nurse anesthetist" means a professional nurse licensed under ch. 441, Stats., who has obtained, through additional education and successful completion of a national examination, a certification as an anesthesia nursing specialist.

(28) "Off-line medical direction" means medical direction that does not involve voice communication provided to EMTs and first responders providing direct patient care.

(29) "On-line medical direction" means medical direction of the activities of an EMT that involves voice communication provided to the EMTs by the medical director or by a physician designated by the medical director.

(30) "On-line medical control physician" means a physician who is designated by the medical director to provide voice communicated medical direction to emergency medical technician and first responder personnel and to assume responsibility for the care provided by emergency medical technician and first responder personnel in response to that direction.

(31) "Out-of-hospital" means care provided to sick or injured persons before or during transportation to a medical facility, including any necessary stabilization of the sick or injured person.

(32) "Pediatric trauma center" means a hospital that is dedicated to providing for the trauma needs of a pediatric patient population and meets the resource requirements outlined by the ACS in chapter 10 of the publication *Resources for Optimal Care of the Injured Patient: 1999"* for verification as a pediatric trauma center. The trauma center may be freestanding or a separate administrative unit in a larger hospital.

Note: The publication, *Resources for Optimal Care of the Injured Patient: 1999*, Committee on Trauma, American College of Surgeons (1998), is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State's Office, and is available for purchase from the American College of Surgery, 633 W. Saint Clair St., Chicago, Illinois 60611-3211. Chapter 10 is titled "*Pediatric Trauma Care.*"

(33) "Performance improvement" means a method of evaluating and improving processes of trauma patient care that emphasizes a multidisciplinary approach to problem solving.

(34) "Physician" means a person licensed under ch. 448, Stats., to practice medicine and surgery.

(35) "Protocol" means a written statement approved by the department and signed and dated by the medical director that lists and describes the steps any out-of-hospital care provider is to follow in assessing and treating a patient.

(36) "Regional trauma advisory council" or "RTAC" means an organized group of healthcare entities and other concerned individuals who have an interest in organizing and improving trauma care within a specified geographic region approved by the department.

(37) "Regional trauma plan" means a written report prepared by an RTAC that meets all of the following criteria:

(a) Identifies the region's current trauma care development strengths and weaknesses.

(b) Describes specific goals for future growth and activities in the region.

(c) Is based on the RTAC's needs assessment.

(38) "Resource hospital" means a hospital in Wisconsin or a bordering state that makes a written commitment to assist the level III coordinating facility of an RTAC to meet the needs required for the development, implementation, maintenance and evaluation of the regional trauma system.

(39) "Rural" means outside a metropolitan statistical area specified under 42 CFR 412.62 (ii) (A) or in a city, village or town with a population of less than 14,000.

(40) "Statewide trauma advisory council" or "STAC" means the entity established by the department to advise the department on a variety of issues pertaining to the establishment and operation of the statewide trauma care system.

(41) "Trauma care system" means a comprehensive and organized approach to facilitating and coordinating a multidisciplinary system response to traumatically injured patients and includes the continuum of care from initial injury detection through definitive care, rehabilitation and injury control.

(42) "Trauma care facility" means a hospital that the department has approved as having the services and capabilities of a level I, II, III or IV trauma care facility.

(43) "Traumatic injury" means major or severe injuries to more than one system of a person's body or major injury to a single system of the body that has the potential of causing death or major disability.

(44) "Trauma registry" means a system for collecting data from hospitals for which the department manages and analyzes the data and disseminates the results.

(45) "Triage" means classifying patients according to the severity of their medical conditions at the scene of an injury or onset of illness and subsequently providing care first to those patients with the greatest medical needs and who are likely to benefit from that care.

(46) "Unclassified hospital" means a hospital that either has chosen not to be a part of Wisconsin's trauma care system, or a hospital that the department has not approved as a level I, II, III or IV trauma care facility.